

HOUSE BILL NO. 933

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions

on \_\_\_\_\_)

(Patron Prior to Substitute--Delegate Robinson)

A BILL to amend and reenact §§ 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to pharmaceutical processors.

**Be it enacted by the General Assembly of Virginia:**

**1. That §§ 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia are amended and reenacted as follows:**

**§ 54.1-3408.3. Certification for use of cannabis oil for treatment.**

A. As used in this section:

"Botanical cannabis" means cannabis that is composed wholly of usable cannabis from the same parts of the same chemovar of cannabis plant.

"Cannabis oil" means any formulation of processed Cannabis plant extract, which may include ~~oil~~ from industrial hemp-extract extracts, including isolates and distillates, acquired by a pharmaceutical processor pursuant to § 54.1-3442.6, or a dilution of the resin of the Cannabis plant that contains ~~at least five milligrams of cannabidiol (CBD) or tetrahydrocannabinolic acid (THC-A) and~~ no more than 10 milligrams of delta-9-tetrahydrocannabinol per dose. "Cannabis oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law, unless it has been grown and processed in the Commonwealth by a registered industrial hemp processor and acquired and formulated ~~with cannabis plant extract~~ by a pharmaceutical processor.

"Cannabis product" means a product that is (i) produced by a pharmaceutical processor, registered with the Board, and compliant with testing requirements and (ii) composed of cannabis oil or botanical cannabis.

26 "Designated caregiver facility" means any hospice or hospice facility licensed pursuant to § 32.1-  
27 162.3, or home care organization as defined in § 32.1-162.7 that provides pharmaceutical services or home  
28 health services, private provider licensed by the Department of Behavioral Health and Developmental  
29 Services pursuant to Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2, assisted living facility  
30 licensed pursuant to § 63.2-1701, or adult day care center licensed pursuant to § 63.2-1701.

31 "Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine,  
32 a physician assistant licensed by the Board of Medicine, or a nurse practitioner jointly licensed by the  
33 Board of Medicine and the Board of Nursing.

34 "Registered agent" means an individual designated by a patient who has been issued a written  
35 certification, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, designated  
36 by such patient's parent or legal guardian, and registered with the Board pursuant to subsection G.

37 "Usable cannabis" means any cannabis plant material, including seeds, but not (i) resin that has  
38 been extracted from any part of the cannabis plant, its seeds, or its resin; (ii) the mature stalks, fiber  
39 produced from the stalks, or any other compound, manufacture, salt, or derivative, mixture, or preparation  
40 of the mature stalks; or (iii) oil or cake made from the seeds of the plant.

41 B. A practitioner in the course of his professional practice may issue a written certification for the  
42 use of cannabis products for treatment or to alleviate the symptoms of any diagnosed condition or disease  
43 determined by the practitioner to benefit from such use. The practitioner shall use his professional  
44 judgment to determine the manner and frequency of patient care and evaluation and may employ the use  
45 of telemedicine, provided that the use of telemedicine includes the delivery of patient care through real-  
46 time interactive audio-visual technology. If a practitioner determines it is consistent with the standard of  
47 care to dispense botanical cannabis to a minor, the written certification shall specifically authorize such  
48 dispensing. If not specifically included on the initial written certification, authorization for botanical  
49 cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing.

50 C. The written certification shall be on a form provided by the ~~Office of the Executive Secretary~~  
51 ~~of the Supreme Court developed in consultation with the Board of Medicine~~ Pharmacy. Such written  
52 certification shall contain the name, address, and telephone number of the practitioner; the name and

53 address of the patient issued the written certification; the date on which the written certification was  
54 made; and the signature or authentic electronic signature of the practitioner. Such written certification  
55 issued pursuant to subsection B shall expire no later than one year after its issuance unless the practitioner  
56 provides in such written certification an earlier expiration. A written certification shall not be issued to a  
57 patient by more than one practitioner during any given time period.

58 D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for the issuance of a  
59 certification for the use of cannabis products for the treatment or to alleviate the symptoms of a patient's  
60 diagnosed condition or disease pursuant to a written certification issued pursuant to subsection B. Nothing  
61 in this section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly  
62 evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for  
63 evaluating or treating medical conditions.

64 E. A practitioner who issues a written certification to a patient pursuant to this section shall register  
65 with the Board and shall hold sufficient education and training to exercise appropriate professional  
66 judgment in the certification of patients. The Board shall not limit the number of patients to whom a  
67 practitioner may issue a written certification. The Board may report information to the applicable licensing  
68 board on unusual patterns of certifications issued by a practitioner.

69 ~~F. A patient who has been issued a written certification shall register with the Board or, if such~~  
70 ~~patient is a minor or an incapacitated adult as defined in § 18.2-369, a patient's parent or legal guardian~~  
71 ~~shall register and shall register such patient with the Board.~~ No patient shall be required to physically  
72 present the written certification after the initial dispensing by any pharmaceutical processor or cannabis  
73 dispensing facility under each written certification, provided that the pharmaceutical processor or cannabis  
74 dispensing facility maintains an electronic copy of the written certification. Pharmaceutical processors  
75 and cannabis dispensing facilities shall electronically transmit, on a weekly basis, all new written  
76 certifications received by the pharmaceutical processor or cannabis dispensing facility to the Board.

77 G. A patient, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such  
78 patient's parent or legal guardian, may designate an individual to act as his registered agent for the purposes  
79 of receiving cannabis products pursuant to a valid written certification. Such designated individual shall

80 register with the Board. The Board may set a limit on the number of patients for whom any individual is  
81 authorized to act as a registered agent.

82 H. Upon delivery of a cannabis-~~oil~~ product by a pharmaceutical processor or cannabis dispensing  
83 facility to a designated caregiver facility, any employee or contractor of a designated caregiver facility,  
84 who is licensed or registered by a health regulatory board and who is authorized to possess, distribute, or  
85 administer medications, may accept delivery of the cannabis-~~oil~~ product on behalf of a patient or resident  
86 for subsequent delivery to the patient or resident and may assist in the administration of the cannabis-~~oil~~  
87 product to the patient or resident as necessary.

88 ~~I. The Board shall promulgate regulations to implement the registration process. Such regulations~~  
89 ~~shall include (i) a mechanism for sufficiently identifying the practitioner issuing the written certification,~~  
90 ~~the patient being treated by the practitioner, his registered agent, and, if such patient is a minor or an~~  
91 ~~incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian; (ii) a process for~~  
92 ~~ensuring that any changes in the information are reported in an appropriate timeframe; and (iii) a~~  
93 ~~prohibition for the patient to be issued a written certification by more than one practitioner during any~~  
94 ~~given time period.~~

95 ~~J. Information obtained under the registration process shall be confidential and shall not be subject~~  
96 ~~to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However,~~  
97 ~~reasonable access to registry information shall be provided to (i) the Chairmen of the House Committee~~  
98 ~~for Courts of Justice and the Senate Committee on the Judiciary, (ii) state and federal agencies or local~~  
99 ~~law enforcement for the purpose of investigating or prosecuting a specific individual for a specific~~  
100 ~~violation of law, (iii) licensed practitioners or pharmacists, or their agents, for the purpose of providing~~  
101 ~~patient care and drug therapy management and monitoring of drugs obtained by a-registered patient, (iv)~~  
102 ~~a pharmaceutical processor or cannabis dispensing facility involved in the treatment of a-registered patient,~~  
103 ~~or (v) a-registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as~~  
104 ~~defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related~~  
105 ~~to such-registered patient.~~

106 **§ 54.1-3442.5. Definitions.**

107 As used in this article:

108 "Botanical cannabis," "cannabis oil," "cannabis product," and "usable cannabis" have the same  
109 meanings as specified in § 54.1-3408.3.

110 "Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board  
111 pursuant to § 54.1-3442.6; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses  
112 cannabis products produced by a pharmaceutical processor to a ~~registered~~ patient, his registered agent, or,  
113 if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal  
114 guardian.

115 "Designated caregiver facility" has the same meaning as defined in § 54.1-3408.3.

116 "Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant  
117 to § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabis oil,  
118 botanical cannabis, and usable cannabis, produces cannabis products, and dispenses cannabis products to  
119 a ~~registered~~ patient pursuant to a written certification, his registered agent, or, if such patient is a minor or  
120 an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian.

121 "Practitioner" has the same meaning as specified in § 54.1-3408.3.

122 "Registered agent" has the same meaning as specified in § 54.1-3408.3.

123 **§ 54.1-3442.6. Permit to operate pharmaceutical processor or cannabis dispensing facility.**

124 A. No person shall operate a pharmaceutical processor or a cannabis dispensing facility without  
125 first obtaining a permit from the Board. The application for such permit shall be made on a form provided  
126 by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical  
127 processor's dispensing area or cannabis dispensing facility. The Board shall establish an application fee  
128 and other general requirements for such application.

129 B. Each permit shall expire annually on a date determined by the Board in regulation. The number  
130 of permits that the Board may issue or renew in any year is limited to one pharmaceutical processor and  
131 up to five cannabis dispensing facilities for each health service area established by the Board of Health.  
132 Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor and  
133 cannabis dispensing facility.

134 C. The Board shall adopt regulations establishing health, safety, and security requirements for  
135 pharmaceutical processors and cannabis dispensing facilities. Such regulations shall include requirements  
136 for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum  
137 equipment and resources; (v) recordkeeping; (vi) labeling, including the potency of each botanical  
138 cannabis product and the amounts recommended by the practitioner or dispensing pharmacist, and  
139 packaging; (vii) routine inspections no more frequently than once annually; (viii) processes for safely and  
140 securely dispensing and delivering in person cannabis products to a ~~registered~~ patient, his registered agent,  
141 or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or  
142 legal guardian; (ix) dosage limitations for cannabis oil that provide that each dispensed dose of cannabis  
143 oil not exceed 10 milligrams of delta-9-tetrahydrocannabinol; (x) a process for the wholesale distribution  
144 of and the transfer of usable cannabis, botanical cannabis, cannabis oil, and cannabis products between  
145 pharmaceutical processors, between a pharmaceutical processor and a cannabis dispensing facility, and  
146 between cannabis dispensing facilities; (xi) an allowance for the sale of devices for administration of  
147 dispensed cannabis products and hemp-based CBD products that meet the applicable standards set forth  
148 in state and federal law, including the laboratory testing standards set forth in subsection M; (xii) an  
149 allowance for the use and distribution of inert product samples containing no cannabinoids for patient  
150 demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for  
151 further distribution or sale, without the need for a written certification; (xiii) a process for acquiring ~~oil~~  
152 ~~from industrial hemp extract and formulating such oil extract with Cannabis plant extract into allowable~~  
153 ~~dosages of cannabis oil~~ extracts and formulating such extracts into cannabis products; and (xiv) an  
154 allowance for the advertising and promotion of the pharmaceutical processor's products and operations,  
155 which shall not limit the pharmaceutical processor from the provision of educational material to  
156 practitioners who issue written certifications and ~~registered~~ patients. The Board shall also adopt  
157 regulations for pharmaceutical processors that include requirements for (a) processes for safely and  
158 securely cultivating Cannabis plants intended for producing cannabis products, (b) the secure disposal of  
159 agricultural waste, and (c) a process for registering cannabis oil products.

160 D. The Board shall require that, after processing and before dispensing any cannabis products, a  
161 pharmaceutical processor shall make a sample available from each batch of cannabis product for testing  
162 by an independent laboratory located in Virginia meeting Board requirements. A valid sample size for  
163 testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and  
164 laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing  
165 or distribution from each homogenized batch of cannabis oil is required to achieve a representative  
166 cannabis oil sample for analysis. A minimum sample size, to be determined by the certified testing  
167 laboratory, from each batch of botanical cannabis is required to achieve a representative botanical cannabis  
168 sample for analysis. Botanical cannabis products shall only be tested for the following: total cannabidiol  
169 (CBD); total tetrahydrocannabinol (THC); terpenes; pesticide chemical residue; heavy metals;  
170 mycotoxins; moisture; and microbiological contaminants. Testing thresholds shall be consistent with  
171 generally accepted cannabis industry thresholds. The pharmaceutical processor may remediate botanical  
172 cannabis or cannabis oil that fails any quality testing standard except pesticides. Following remediation,  
173 all remediated botanical cannabis or cannabis oil shall be subject to laboratory testing and approved upon  
174 satisfaction of applicable testing standards applied to cannabis oil generally, which shall not be more  
175 stringent than initial testing prior to remediation. ~~If the a batch of botanical cannabis fails retesting after~~  
176 ~~remediation, it shall be considered usable cannabis and may be processed into cannabis oil, unless the~~  
177 ~~failure is related to pesticide requirements, in which case the batch shall not be considered usable cannabis~~  
178 ~~and shall not be processed into cannabis oil.~~ Stability testing shall not be required for any cannabis oil  
179 product with an expiration date assigned by the pharmaceutical processor of six months or less from the  
180 date of ~~packaging~~ the cannabis product registration approval. Stability testing required for assignment of  
181 an expiration date longer than six months shall be limited to microbial testing, on a pass/fail basis, and  
182 potency testing, on a 10 percent deviation basis, of active ingredients.

183 E. A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances  
184 registration certificate pursuant to § 54.1-3423 and shall comply with quality standards established by the  
185 Board in regulation.

186 F. Every pharmaceutical processor's dispensing area or cannabis dispensing facility shall be under  
187 the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor or  
188 cannabis dispensing facility. The pharmaceutical processor shall ensure that security measures are  
189 adequate to protect the cannabis from diversion at all times, and the pharmacist-in-charge shall have  
190 concurrent responsibility for preventing diversion from the dispensing area.

191 Every pharmaceutical processor shall designate a person who shall have oversight of the  
192 cultivation and production areas of the pharmaceutical processor and shall provide such information to  
193 the Board. The Board shall direct all communications related to enforcement of requirements related to  
194 cultivation and production of cannabis oil products by the pharmaceutical processor to such designated  
195 person.

196 G. The Board shall require the material owners of an applicant for a pharmaceutical processor or  
197 cannabis dispensing facility permit to submit to fingerprinting and provide personal descriptive  
198 information to be forwarded along with his fingerprints through the Central Criminal Records Exchange  
199 to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information  
200 regarding the applicant's material owners. The cost of fingerprinting and the criminal history record search  
201 shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the  
202 criminal history background check to the Board or its designee, which shall be a governmental entity. A  
203 pharmaceutical processor shall maintain evidence of criminal background checks for all employees and  
204 delivery agents of the pharmaceutical processor. Criminal background checks of employees and delivery  
205 agents may be conducted by any service sufficient to disclose any federal and state criminal convictions.

206 H. In addition to other employees authorized by the Board, a pharmaceutical processor may  
207 employ individuals who may have less than two years of experience (i) to perform cultivation-related  
208 duties under the supervision of an individual who has received a degree in a field related to the cultivation  
209 of plants or a certification recognized by the Board or who has at least two years of experience cultivating  
210 plants, (ii) to perform extraction-related duties under the supervision of an individual who has a degree in  
211 chemistry or pharmacology or at least two years of experience extracting chemicals from plants, and (iii)

212 to perform duties at the pharmaceutical processor and cannabis dispensing facility upon certification as a  
213 pharmacy technician.

214 I. A pharmaceutical processor to whom a permit has been issued by the Board may establish up to  
215 five cannabis dispensing facilities for the dispensing of cannabis products that have been cultivated and  
216 produced on the premises of a pharmaceutical processor permitted by the Board. Each cannabis dispensing  
217 facility shall be located within the same health service area as the pharmaceutical processor.

218 J. No person who has been convicted of a felony under the laws of the Commonwealth or another  
219 jurisdiction within the last five years shall be employed by or act as an agent of a pharmaceutical processor  
220 or cannabis dispensing facility.

221 K. Every pharmaceutical processor or cannabis dispensing facility shall adopt policies for pre-  
222 employment drug screening and regular, ongoing, random drug screening of employees.

223 L. A pharmacist at the pharmaceutical processor's dispensing area and the cannabis dispensing  
224 facility shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician  
225 trainees who can be safely and competently supervised at one time; however, no pharmacist shall supervise  
226 more than six persons performing the duties of a pharmacy technician at one time in the pharmaceutical  
227 processor's dispensing area or cannabis dispensing facility.

228 M. A pharmaceutical processor may acquire industrial hemp ~~extract~~ extracts grown and processed  
229 in Virginia, and in compliance with state or federal law, from a registered industrial hemp dealer or  
230 processor. A pharmaceutical processor may process and formulate such ~~extract with cannabis plant~~ extract  
231 extracts into an allowable dosage of cannabis ~~oil~~ product. Industrial hemp ~~extract~~ extracts acquired and  
232 formulated by a pharmaceutical processor ~~is~~ are subject to the same third-party testing requirements that  
233 may apply to cannabis plant extract. Testing shall be performed by a laboratory located in Virginia and in  
234 compliance with state law governing the testing of cannabis products. The industrial hemp dealer or  
235 processor shall provide such third-party testing results to the pharmaceutical processor before industrial  
236 hemp ~~extract~~ extracts may be acquired.

237 N. With the exception of § 2.2-4031, neither the provisions of the Administrative Process Act (§  
238 2.2-4000 et seq.) nor public participation guidelines adopted pursuant thereto shall apply to the adoption

239 of any regulation pursuant to this section. Prior to adopting any regulation pursuant to this section, the  
240 Board of Pharmacy shall publish a notice of opportunity to comment in the Virginia Register of  
241 Regulations and post the action on the Virginia Regulatory Town Hall. Such notice of opportunity to  
242 comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation;  
243 and (iii) the name, address, and telephone number of the agency contact person responsible for receiving  
244 public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such  
245 notice for submittals of public comment. The legislative review provisions of subsections A and B of §  
246 2.2-4014 shall apply to the promulgation or final adoption process for regulations pursuant to this section.  
247 The Board of Pharmacy shall consider and keep on file all public comments received for any regulation  
248 adopted pursuant to this section.

249 O. The Board shall register all cannabis products that meet testing, labeling, and packaging  
250 standards.

251 **§ 54.1-3442.7. Dispensing cannabis products; report.**

252 A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis  
253 products only in person to (i) a patient who is a Virginia resident or temporarily resides in Virginia ~~as~~  
254 ~~made evident to the Board, and~~ has been issued a valid written certification, ~~and is registered with the~~  
255 ~~Board pursuant to § 54.1-3408.3;~~ (ii) such patient's registered agent; or (iii) if such patient is a minor or  
256 an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia  
257 resident or temporarily resides in Virginia ~~as made evident to the Board and is registered with the Board~~  
258 ~~pursuant to § 54.1-3408.3.~~ A companion may accompany a ~~registered~~ patient into a pharmaceutical  
259 processor's dispensing area or cannabis dispensing facility. Prior to the initial dispensing of cannabis ~~oil~~  
260 products pursuant to each written certification, a pharmacist or pharmacy technician employed by the  
261 pharmaceutical processor or cannabis dispensing facility shall make and maintain, on site or remotely by  
262 electronic means, for two years a paper or electronic copy of the written certification that provides an  
263 exact image of the document that is clearly legible; shall view, in person or by audiovisual means, a current  
264 photo identification of the patient, registered agent, parent, or legal guardian; and shall verify current board  
265 registration of the practitioner and the corresponding ~~patient, registered agent, parent, or legal guardian if~~

266 applicable. Thereafter, an initial dispensing may be delivered to the patient, registered agent, parent, legal  
267 guardian, or designated caregiver facility. Prior to any subsequent dispensing of cannabis-~~oil~~ products  
268 pursuant to each written certification, an employee or delivery agent shall view a current photo  
269 identification of the patient, registered agent, parent, or legal guardian and the current board registration  
270 issued to the ~~patient, registered agent, parent, or legal guardian~~ if applicable. No pharmaceutical processor  
271 or cannabis dispensing facility shall dispense more than a 90-day supply of a cannabis product, as  
272 determined by the dispensing pharmacist or certifying practitioner, for any patient during any 90-day  
273 period; however, a pharmaceutical processor or cannabis dispensing facility may dispense more than one  
274 cannabis product to a patient at one time. No more than four ounces of botanical cannabis shall be  
275 dispensed for each 30-day period for which botanical cannabis is dispensed. A pharmaceutical processor  
276 or cannabis dispensing facility may dispense less than a 90-day supply. In determining the appropriate  
277 amount of a cannabis product to be dispensed to a patient, a pharmaceutical processor or cannabis  
278 dispensing facility shall consider all cannabis products dispensed to the patient and adjust the amount  
279 dispensed accordingly.

280 B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis  
281 products produced on the premises of a pharmaceutical processor permitted by the Board or cannabis-~~oil~~  
282 products that ~~has~~ have been formulated with ~~oil~~ extracts from industrial hemp acquired by a  
283 pharmaceutical processor from a registered industrial hemp dealer or processor pursuant to § 54.1-3442.6.  
284 A pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

285 C. The Board shall report annually by December 1 to the Chairmen of the House Committee for  
286 Health, Welfare and Institutions and the Senate Committee on Education and Health on the operation of  
287 pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board, ~~including the~~  
288 ~~number of practitioners, patients, registered agents, and parents or legal guardians of patients who have~~  
289 ~~registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.~~

290 D. The concentration of delta-9-tetrahydrocannabinol in any cannabis product on site may be up  
291 to 10 percent greater than or less than the level of delta-9-tetrahydrocannabinol measured for labeling. A  
292 pharmaceutical processor and cannabis dispensing facility shall ensure that such concentration in any

293 cannabis product on site is within such range. A pharmaceutical processor producing cannabis products  
294 shall establish a stability testing schedule of cannabis products.

295 **2. That the Board of Pharmacy shall amend its regulations, including subsection A of 18VAC110-**  
296 **60-280 of the Virginia Administrative Code, to permit the use of hydrocarbon-based solvents, and**  
297 **any other generally accepted technology, in the cultivation, extraction, production, or**  
298 **manufacturing process of cannabis products.**

299 **3. That the Board of Pharmacy shall amend its regulations, including subsection B of 18VAC110-**  
300 **60-330 of the Virginia Administrative Code, to (i) require only the presence of a pharmacist or the**  
301 **responsible party to witness destruction and disposal of green waste, extracts, and cannabis oil, as**  
302 **applicable; (ii) allow for disposal of green waste by incineration, inert composting, or any other**  
303 **means of disposal or destruction; and (iii) allow a pharmaceutical processor to sell or otherwise**  
304 **distribute inert composted green waste.**

305 **4. That the Board of Pharmacy shall permit pharmaceutical processors to engage in wholesale**  
306 **transactions of bulk cannabis oil, botanical cannabis, and usable cannabis and amend its**  
307 **regulations, including subsection A of 18VAC110-60-251 of the Virginia Administrative Code, to**  
308 **remove the requirements that wholesale transactions of bulk cannabis oil, botanical cannabis, and**  
309 **usable cannabis from any lot or batch (i) must have passed the tests required in subsections G and**  
310 **H of 18VAC110-60-300 of the Virginia Administrative Code and (ii) are packaged and labeled for**  
311 **sale with an appropriate expiration date in accordance with 18VAC110-60-300 of the Virginia**  
312 **Administrative Code. The regulations shall state that wholesale cannabis oil, botanical cannabis,**  
313 **and usable cannabis shall be packaged in a tamper-evident container and labeled with (a) the seller's**  
314 **name and address; (b) the buyer's name and address; (c) the quantity or weight of the cannabis oil,**  
315 **botanical cannabis, or usable cannabis in each container; (d) identification of the contents of the**  
316 **container, including a brief description of the type or form of cannabis oil, botanical cannabis, or**  
317 **usable cannabis and the strain name, as appropriate; (e) a unique serial number that will match a**  
318 **cannabis product with the cultivator and manufacturer and lot or batch number to facilitate any**  
319 **warnings or recalls that the Board of Pharmacy or any successor governmental or quasi-**

320 governmental body authorized to regulate cannabis or the original pharmaceutical processor deems  
321 appropriate; (f) the date of laboratory testing and the name and address of the testing laboratory;  
322 (g) the dates of harvest and packaging; and (h) an expiration date.

323 5. That the Board of Pharmacy shall amend the pharmaceutical processor permit application to  
324 include designation of a corporate point of contact who shall receive copies of all investigative and  
325 disciplinary communications sent to the pharmacist in charge or responsible party.

326 6. That the Board of Pharmacy shall amend its regulations to allow pharmaceutical processors to  
327 engage in marketing activity, inclusive of product, program, company, and related communications  
328 other than those marketing activities that (i) include false or misleading statements; (ii) promote  
329 excessive consumption; (iii) depict a person younger than 21 years of age consuming cannabis; (iv)  
330 include any image designed or likely to appeal to minors, specifically including cartoons, toys,  
331 animals, children, or any other likeness to images, characters, or phrases that are popularly used to  
332 advertise to children; (v) depict products or product packaging or labeling that bears reasonable  
333 resemblance to any product legally available for consumption as a candy or that promotes cannabis  
334 consumption; or (vi) contain any seal, flag, crest, coat of arms, or other insignia that is likely to  
335 mislead registered patients or the general public to believe that the cannabis product has been  
336 endorsed, made, or used by the Commonwealth of Virginia or any of its representatives except  
337 where specifically authorized.

338 7. That the Board of Pharmacy shall amend its regulations, including subsection B of 18VAC110-  
339 60-285 of the Virginia Administrative Code, to include the following exceptions: (i) where the total  
340 tetrahydrocannabinol (THC) concentration is less than 5 milligrams per dose, the concentration of  
341 THC shall be within 0.5 milligrams per dose and (ii) where the total cannabidiol (CBD)  
342 concentration is less than 5 milligrams per dose, the concentration of total CBD shall be within 0.5  
343 milligrams per dose.

344 8. That the Board of Pharmacy shall amend its regulations, including 18VAC110-60-285 and  
345 18VAC110-60-290 of the Virginia Administrative Code, in addition to its product registration form,

346 to permit labeling of cannabis products with an expiration date assigned by the pharmaceutical  
347 processor of six months or less from the date of the cannabis product registration approval.

348 9. That the Board of Pharmacy (the Board) shall maintain an electronic database of certified  
349 patients as reported to the Board by pharmaceutical processors and cannabis dispensing facilities.

350 The Board may utilize the information in this database, in conjunction with information reported  
351 to the prescription monitoring program, to investigate any fraudulent or aberrant certifications.

352 10. That the Board of Pharmacy may assess and collect regulatory fees from each pharmaceutical  
353 processor in an amount sufficient to implement the provisions of this act.

354 11. That the Board of Pharmacy's initial adoption of regulations necessary to implement the  
355 provisions of this act shall be exempt from the Administrative Process Act (§ 2.2-4000 et seq. of the  
356 Code of Virginia), except that the Board of Pharmacy shall provide an opportunity for public  
357 comment on the regulations prior to adoption of such regulations.

358 12. That the Board of Pharmacy shall amend and promulgate regulations in accordance with this  
359 act by September 15, 2022.

360 #